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*Attorneys for Defendants Wockhardt USA LLC and Wockhardt Ltd.*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

NOVARTIS PHARMACEUTICALS  
CORPORATION,

Plaintiff,

v.

ACTAVIS LLC; APOTEX, INC.;  
APOTEX, CORP.; GLAND PHARMA  
LTD.; DR. REDDY'S LABORATORIES,  
INC.; DR. REDDY'S LABORATORIES  
LTD.; EMCURE PHARMACEUTICALS  
USA, INC.; EMCURE  
PHARMACEUTICALS, LTD; HOSPIRA,

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Civil Action No. 13-cv-1028-SDW-MCA

INC.; PHARMACEUTICS	)
INTERNATIONAL INC.; SAGENT	)
PHARMACEUTICALS, INC.; ACS	)
DOBFAR INFO S.A.; STRIDES, INC.;	)
AGILA SPECIALTIES PRIVATE LTD.;	)
SUN PHARMA GLOBAL FZE;	)
CARACO PHARMACEUTICAL	)
LABORATORIES, LTD; SUN	)
PHARMACEUTICAL INDUSTRIES	)
LTD.; WOCKHARDT USA LLC; and	)
WOCKHARDT LTD.	)
Defendants.	)

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**DECLARATION OF KAREN A. CONFOY IN SUPPORT OF  
WOCKHARDT USA LLC AND WOCKHARDT LTD.'S REPLY TO THEIR MOTION  
TO DISMISS COUNT II OF THE CORRECTED AMENDED COMPLAINT**

I, KAREN A. CONFOY, hereby declare as follows:

1. I am counsel for Defendants Wockhardt USA LLC and Wockhardt Limited (collectively "Wockhardt") in the above-captioned action and in Civil Action No. 12-3967 (SDW/MCA). I submit this declaration in support of Wockhardt's Reply to Their Motion to Dismiss Count II of the Corrected Amended Complaint.

2. I am an attorney at law admitted to practice before the United States District Court for the District of New Jersey. I am a partner at Fox Rothschild, LLP. Unless otherwise stated, the facts set forth in this declaration are true and of my own personal knowledge, and, if called upon to do so, I could and would testify competently to them.

3. Attached hereto as **Exhibit 1** are a true and correct copies of the FDA's Approved Drug Products regarding Dr. Reddy's Laboratory, Emcure Pharmaceuticals, and Hospira Inc., available on the FDA's website at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=SearchDrugDetails>, accessed on May 10, 2013.

4. Attached hereto as **Exhibit 2** is a true and correct copy of the FDA's Approved Drug Products list for zoledronic acid available on the FDA's website at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=ZOLEDRONIC%20ACID>, accessed on May 10, 2013.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: May 13, 2013

/s/ Karen A. Confoy

Karen A. Confoy  
kconfoy@foxrothschild.com

Counsel for Wockhardt USA LLC and  
Wockhardt Limited

# **EXHIBIT 1**

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## Drugs@FDA: FDA Approved Drug Products



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### Drug Details

<b>Drug Name(s)</b>	<b>ZOLEDRONIC ACID</b>
<b>FDA Application No.</b>	<b>(ANDA) 091363</b>
<b>Active Ingredient(s)</b>	<b>ZOLEDRONIC ACID</b>
<b>Company</b>	<b>DR REDDYS LABS LTD</b>
<b>Original Approval or Tentative Approval Date</b>	<b>March 29, 2013</b>

- [Therapeutic Equivalents](#)
- [Approval History, Letters, Reviews, and Related Documents](#)
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### Products on Application (ANDA) #091363

Click on a column header to re-sort the table:

<a href="#">Drug Name</a>	<a href="#">Active Ingredients</a>	<a href="#">Strength</a>	<a href="#">Dosage Form/Route</a>	<a href="#">Marketing Status</a>	<a href="#">RLD</a>	<a href="#">TE Code</a>
ZOLEDRONIC ACID	ZOLEDRONIC ACID	EQ 5MG BASE/100ML	INJECTABLE; INJECTION	Prescription	No	AP

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### Drug Details

<b>Drug Name(s)</b>	<b>ZOLEDRONIC ACID</b>
<b>FDA Application No.</b>	<b>(ANDA) 201801</b>
<b>Active Ingredient(s)</b>	<b>ZOLEDRONIC ACID</b>
<b>Company</b>	<b>EMCURE PHARMS LTD</b>
<b>Original Approval or Tentative Approval Date</b>	<b>March 29, 2013</b>

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### Products on Application (ANDA) #201801

Click on a column header to re-sort the table:

<a href="#">Drug Name</a>	<a href="#">Active Ingredients</a>	<a href="#">Strength</a>	<a href="#">Dosage Form/Route</a>	<a href="#">Marketing Status</a>	<a href="#">RLD</a>	<a href="#">TE Code</a>
ZOLEDRONIC ACID	ZOLEDRONIC ACID	EQ 5MG BASE/100ML	INJECTABLE; INJECTION	Prescription	No	AP

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### Drug Details

<b>Drug Name(s)</b>	<b>ZOLEDRONIC ACID</b>
<b>FDA Application No.</b>	<b>(ANDA) 202837</b>
<b>Active Ingredient(s)</b>	<b>ZOLEDRONIC ACID</b>
<b>Company</b>	<b>HOSPIRA INC</b>
<b>Original Approval or Tentative Approval Date</b>	<b>April 5, 2013</b>

- [Therapeutic Equivalents](#)
- [Approval History, Letters, Reviews, and Related Documents](#)
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### Products on Application (ANDA) #202837

Click on a column header to re-sort the table:

<a href="#">Drug Name</a>	<a href="#">Active Ingredients</a>	<a href="#">Strength</a>	<a href="#">Dosage Form/Route</a>	<a href="#">Marketing Status</a>	<a href="#">RLD</a>	<a href="#">TE Code</a>
ZOLEDRONIC ACID	ZOLEDRONIC ACID	EQ 5MG BASE/100ML	INJECTABLE; IV (INFUSION)	Prescription	No	AP

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### Overview

**Drug Name** ZOLEDRONIC ACID  
**Active Ingredient(s)** • ZOLEDRONIC ACID  
**Form(s) and Strength(s) Available** • INJECTABLE; INJECTION: 4MG ; 4MMG ; 5MG/100ML ; EQ 5MG BASE/100ML  
• INJECTABLE; IV (INFUSION): EQ 4MG BASE/5ML ; EQ 4MG BASE/VIAL ; EQ 5MG BASE/100ML

Details about drugs are organized by FDA Application Number (NDA or ANDA or BLA).

**Click on a drug name or application number to view drug details:**

**Click on a column header to re-sort the table:**

Drug Name and FDA Application Number	Label Info	Dosage Form/Route	Strength	Marketing Status	Company
<a href="#">ZOLEDRONIC ACID (ANDA # 078533)</a>	Not Available	INJECTABLE; IV (INFUSION)	EQ 4MG BASE/5ML	None (Tentative Approval)	APOTEX INC
<a href="#">ZOLEDRONIC ACID (ANDA # 078576)</a>	Not Available	INJECTABLE; IV (INFUSION)	EQ 4MG BASE/VIAL	None (Tentative Approval)	TEVA
<a href="#">ZOLEDRONIC ACID (ANDA # 078580)</a>	Not Available	INJECTABLE; IV (INFUSION)	EQ 4MG BASE/VIAL	None (Tentative Approval)	PARENTERAL TEVA
<a href="#">ZOLEDRONIC ACID (ANDA # 090018)</a>	Not Available	INJECTABLE; IV (INFUSION)	EQ 4MG BASE/VIAL	Prescription	PARENTERAL SUN PHARMA
<a href="#">ZOLEDRONIC ACID (ANDA # 090330)</a>	Not Available	INJECTABLE; IV (INFUSION)	EQ 4MG BASE/5ML	None (Tentative Approval)	GLOBAL PHARMAFORCE
<a href="#">ZOLEDRONIC ACID (ANDA # 090621)</a>	Not Available	INJECTABLE; IV (INFUSION)	EQ 4MG BASE/5ML	None (Tentative Approval)	HOSPIRA INC
<a href="#">ZOLEDRONIC ACID (ANDA # 090709)</a>	Not Available	INJECTABLE; IV (INFUSION)	EQ 4MG BASE/5ML	None (Tentative Approval)	HOSPIRA INC
<a href="#">ZOLEDRONIC ACID (ANDA # 091170)</a>	Not Available	INJECTABLE; IV (INFUSION)	EQ 4MG BASE/5ML	Prescription	PHARMACEUTICS
<a href="#">ZOLEDRONIC ACID (ANDA # 091186)</a>	Not Available	INJECTABLE; IV (INFUSION)	EQ 4MG BASE/5ML	Prescription	DR REDDYS LABS LTD
<a href="#">ZOLEDRONIC ACID (ANDA # 091187)</a>	Not Available	INJECTION	4MMG	None (Tentative Approval)	DR REDDYS LABS LTD
<a href="#">ZOLEDRONIC ACID (ANDA # 091363)</a>	Not Available	INJECTABLE; INJECTION	EQ 5MG BASE/100ML	Prescription	DR REDDYS LABS LTD
<a href="#">ZOLEDRONIC ACID (ANDA # 091364)</a>	Not Available	INJECTABLE; INJECTION	5MG/100ML	None (Tentative Approval)	DR REDDYS LABS LTD
<a href="#">ZOLEDRONIC ACID (ANDA # 201783)</a>	Not Available	INJECTABLE; IV (INFUSION)	EQ 4MG BASE/5ML	Prescription	EMCURE
<a href="#">ZOLEDRONIC ACID (ANDA # 201801)</a>	Not Available	INJECTABLE; INJECTION	EQ 5MG BASE/100ML	Prescription	PHARMS LTD
<a href="#">ZOLEDRONIC ACID (ANDA # 202472)</a>	Not Available	INJECTABLE; IV (INFUSION)	EQ 4MG BASE/5ML	Prescription	EMCURE
<a href="#">ZOLEDRONIC ACID (ANDA # 202571)</a>	Not Available	INJECTABLE; IV (INFUSION)	EQ 4MG BASE/5ML	Prescription	PHARMS LTD
<a href="#">ZOLEDRONIC ACID (ANDA # 202650)</a>	Not Available	INJECTABLE; IV (INFUSION)	EQ 4MG BASE/5ML	Prescription	ACTAVIS INC
<a href="#">ZOLEDRONIC ACID (ANDA # 202746)</a>	Not Available	INJECTABLE; IV (INFUSION)	EQ 4MG BASE/5ML	Prescription	PHARMS
<a href="#">ZOLEDRONIC ACID (ANDA # 202837)</a>	Not Available	INJECTABLE; IV (INFUSION)	EQ 5MG BASE/100ML	Prescription	AGILA SPECLTS
<a href="#">ZOLEDRONIC ACID (NDA # 203231)</a>	Not Available	INJECTION	4MG	None (Tentative Approval)	SUN PHARMA GLOBAL
	Not Available	INJECTION			HOSPIRA INC
	Not Available	INJECTION			ACS DOBFAR INFO SA

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